REMARKS

Claims 1-34 are all the claims pending in the application. Claims 27-34 have been withdrawn as non-elected claims.

The claims have been amended as discussed below. No new matter has been entered. Accordingly, entry of the Amendment is hereby requested along with reconsideration and review on the merits.

Formal Matters

Applicants appreciate that the Examiner has acknowledged Applicants' claim for domestic priority under 35 U.S.C. § 120 and/or 121.

Claim Rejections - 35 USC § 112

Claims 2-11, 13-17, and 19-26 have been rejected under 35 USC 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants respond that by amendment, the metes and bounds of Claims 2 and 15 are now rendered certain as the sentences no longer lack a period.

Regarding Claim 3, line 3, Applicants have corrected an apparent misspelling by replacing "least1" with least 1.

Claim 4 recites the limitation "the herbal active agent" in line 1. The Examiner asserts that Claim 4 lacks clear antecedent basis for this limitation in the claim. Applicants traverse by

submitting that clear antecedent basis for "the herbal active agent" is evident in the phrase "at least one herbal active agent or homeopathic active agent" of Claim 1.

Claim 4, line 2, is amended to delete "either" as suggested by the Examiner.

Claim 5 has been amended to more clearly recite the limitation that "the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil and mixtures thereof". The term "the herbal active agent" finds support at least from Claim 1 from which it depends upon.

Claim 6 now recites the limitation "the herbal active agent or homeopathic active agent" which has antecedent basis in Claim 1 which Claim 6 is now dependent upon. Applicants submit that Claim 6 is a proper Markush group in reciting both plants and herbal plants.

Claim 6, line 3, now recites Salvia officinalis to replace the abbreviation "Salvia offinc.".

Regarding Claim 6, line 3, the apparent misspelling has been corrected by replacing "Myrrah" with Myrrh.

Regarding Claim 6, line 4, the apparent misspelling has been corrected by replacing "Phytolaca" with Phytolacca.

The apparent typographical error appearing in Claim 6, line 6 has been corrected by replacing the period "." which appears after "Sage" with a comma.

With regard to Claim 6, line 7, the term "Propolis" no longer renders the recitation of the Markush group improper because although "Propolis" is not an herb, but a material derived from the hives of bees, it is still consistent with "herbal active agent or homeopathic active agent".

Regarding Claim 6, line 7, the apparent misspelling has been corrected by replacing "Barberine" with berberine.

Regarding Claim 6, line 8, the apparent misspelling has been corrected by replacing "berberidaccae" with Berberidaceae.

Claim 7 now recites the limitation "wherein the herbal active agent is at least one essential oil selected from..." in line 1 which finds antecedent basis, for example, in Claim 5 from which it is dependent upon.

Regarding Claim 7, line 3, the apparent misspelling has been corrected by replacing "cedrwood" with cedarwood.

Regarding Claim 7, line 4, the apparent misspelling has been corrected by replacing "rosmarinus offencinalis" with Rosmarinus officinalis.

Regarding Claim 7, line 6, the apparent misspelling has been corrected by replacing "origano" with oregano.

Claim 7 has been corrected to replace the term "pomella" with pomelo.

Claim 8 now recites "the herbal active agent is at least one essential oil selected from ..." which now has clear antecedent basis for this limitation in Claim 5.

Claims 9 and 10 now recite "the herbal active agent" which now has clear antecedent basis for this limitation in the claims from which they depend upon, now changed to Claims 6 and 5, respectively. Furthermore, Claim 10 now recites "wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at

least one of myrcene, a- pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene." Support can be found, for example, at the bottom of page 9, and pages 19-20 and 33 of the specification as originally filed.

Claim 11 is has been corrected to replace the term "pomella" with pomelo.

Claim 13, line 2, is no longer rendered vague and indefinite by the phrase "in a synergistic and effective amount" because that phrase has now been deleted. Accordingly, the metes and bounds of this claim are now clearly and adequately delineated.

Claim 14 now recites the limitation "based on the amount of the at least one herbal active agent or homeopathic active agent" in lines 2-3 which has antecedent basis in Claim 1.

Claim 15 now recites "anesthetic agent" such that the limitation "anesthetic agent" in line 1 of Claim 16 has clear antecedent basis.

Claims 16 and 17 are no longer allegedly vague and indefinite as the phrase "is in the form of the base or an acid-addition salt or both forms" at the end of the claims has been deleted. Now, the claims recite "...selected from the group consisting of at least one base or acid-addition salt of ....".

Claim 17 now recites the limitation "the non-herbal active agent" in line 1 which finds support in Claim 15.

Applicants amend Claim 18 to clarify their claimed invention. Claim 18 now recites "[t]he composition of claim 4, further comprising Carnallite or a salt of Carnallite, which improves the activity of the herbal active agents."

Claim 19 now recites the limitation "the herbal active agent" in line 1 which finds support in Claim 4.

Regarding claim 19, the phrase "and the like" has been deleted. Additionally, a Markush grouping has been added to clarify the Applicants' invention.

Regarding Claims 20 and 21, the apparent misspelling in line 1 of Claim 20 has been corrected by replacing "cirton" with citron. Furthermore, the term "active agent" has been replaced with "composition".

Regarding claim 21, the phrase "such as" has been replaced with a Markush grouping to clarify the Applicants' claimed invention.

Claim 22 has been amended to recite "wherein the solid bioadhesive carrier is selected from a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof'. It is clear that the phrase refers to the "pharmaceutically acceptable solid bioadhesive carrier" instead of the "self-bioadhesive composition".

With regard to Claim 23, line 5, the apparent misspelling has been corrected by replacing "gaur-gum" with guar-gum.

Claim 24 now recites the limitation "said composition" in line 2 which finds antecedant support in Claim 22.

Claim 25 now depends on Claim 24 instead of Claim 22 so that "said enhancers" in line 1 has sufficient antecedent basis. Furthermore, the apparent misspelling has been corrected by replacing "enyzme" with enzyme.

The Examiner asserts that the metes and bounds of Claim 25 are made uncertain by "limonene derivatives" because it is unclear as to what constitutes "limonene derivatives" or how closely related the derivatives must be to considered derivatives of limonene. Applicants respond that one of ordinary skill in the art would understand the term "limonene derivatives". In order to advance prosecution, Applicants have amended the claim to recite "wherein said enhancers are selected from salts of bile acid and limonene." In making this change, Applicants submit that the term "limonene" will include derivatives of limonene.

Claim 26 is amended to recite "[a] composition according to claim 22 wherein said solid adhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polyalkenyl polyether, carboxymethylcellulose, hydroxyethylcellulose and mixtures thereof." Support can be found, for example, at page 13, lines 11-12. Thus, it is certain as to the subject matter which Applicants intend to direct the invention.

Claim 26, line 2, recites the term "lightly crosslinked". Applicants respectfully submit that the term "lightly crosslinked" in claim 26 is an art recognized term that one of skill in the art would readily understand. See also, Applicants' disclosure in the specification at page 13, lines 3-9.

Accordingly, Applicants submit that the various rejections under 35 U.S.C. § 112 have now been obviated so that withdrawal of the rejections is now in order and respectfully requested.

Claim Objections

Claim 6 has been objected to under 37 CFR 1.75(c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants respond that Claim 6 has been amended to now depend from Claim 1 which Applicants submit overcomes the Examiner's objection.

Claims 20 and 21 have been objected to under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have amended Claims 20 and 21 directed to a "composition" instead of "The active agent" which Applicants submit overcomes the Examiner's objection.

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants have amended Claim 25 to now depend from Claim 24 which Applicants submit overcomes the Examiner's objection.

Accordingly, Applicants submit that the various objections have now been obviated so that withdrawal of the objections is now in order and respectfully requested.

Claim Rejections - 35 USC § 102

Claims 1, 4, 5, 7, 15 and 22-24 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ronchi et al for the reasons cited in the Office Action.

In Claim 1, Applicants claim a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising (a) a therapeutically effective amount of at least one herbal or homeopathic active agent; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 90 percent based on the weight of the whole composition.

The Examiner asserts that Ronchi teaches, e.g., a solid, self-bioadhesive in the form of a lozenge composition for topical application that adheres to the oral mucosal tissue comprising at least one active ingredient in admixture with muco-adhesive polymers, and conventional carriers and excipients, on page 2, Column 2, lines 28-34.

Applicants respectfully traverse and submit that the reference does not anticipate the claimed subject matter.

Applicants submit that Ronchi describes lozenges composed of common antimicrobial agents such as iodine, benzalkonium chloride, and cetylpyridinium chloride as active agents. The lozenges are made from about 99.5% of highly water soluble sugars like glucose and saccharose with less than 0.5% of a bioadhesive polymer. These lozenges have no ability to stick to mucosal tissue as the amount of adhesive polymer is negligible. The lozenges are basically candies that have some antibacterial agent release from them when having the Candies in the mouth.

Applicants submit that Ronchi is not related to the subject matter of the present application because:

1. Ronchi des not contain a bioadhesive and is not a bioadhesive, and it has no capabilities to stick to mucosal tissue, which is a claimed feature of the present invention.

2. The lozenges of Ronchi release common antibacterial agents, and there is no use or mention of herbal bioactive agents. The herbals used in Ronchi are in minute amounts (<0.1%) as flavorings. Applicants claim therapeutically effective amounts of at least one herbal active agent or homeopathic active agent.

3. The actives are released to the entire mouth cavity, with no specificity to a certain site such as an ulcer, etc.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Claims 1, 4, 5, 7, 9, 19, 22 and 24 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Friedman et al. (US 5,942,244) with evidence provided by Lawless for the reasons cited in the Office Action.

The Examiner asserts that Friedman teaches, e.g., a solid, self-bioadhesive composition for topical application in the form of a tablet comprising a therapeutically effective amount of an herbal medication and a polymeric matrix material, e.g., ethyl cellulose, a release enhancer and a filler.

The Examiner recognizes that Friedman does not expressly teach his composition as a self-bioadhesive composition. However, the Examiner asserts that the ingredients and the amounts of the ingredients taught by Friedman are the same as those instantly claimed; therefore,

the functional effect or property must be the same. Moreover, Friedman is asserted to teach that the slow release tablets for oral administration permit a prolonged period of contact between the medication and the buccal and gingiva mucosa of the mouth.

Applicants respectfully traverse and submit that the reference does not anticipate the claimed subject matter.

Applicants submit that Friedman describes non-adhesive tablets that release herbal extracts. The tablets are made of ethyl cellulose as the main polymer component. Ethyl cellulose is a highly hydrophobic polymer with no interaction with hydrophilic surfaces. The tablets do not adhere to the oral cavity because they do not contain a bioadhesive polymer, it is simply a matrix releasing system which is not relevant to the present application.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Claims 1, 4, 5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Tapolsky et al. (US 6,159,498).

The Examiner asserts that Tapolsky teaches, e.g, a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising a therapeutically effective amount of at least one herbal active agent and a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 5-95% by weight of the total composition, and wherein the bioadhesive comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose. Tapolsky is further asserted as teaching that the bioadhesive

composition is in the form of a disk having two layers; an adhesive layer and a non-adhesive backing layer and also where the adhesive layer comprises a film forming polymer which may be crosslinked.

Applicants respectfully traverse and submit that the reference does not anticipate the claimed subject matter.

Tapolsky et al. describes films that adhere to mucosal tissue and release common drugs for systemic and topical tissue. The films are prepared by casting aqueous solutions of hydroxy ethyl cellulose and hydroxy propyl cellulose and oven dried to form a non-adhesive film. Adhesive films were prepared from hydroxyethyl cellulose and polyacrylic acid. The residence time for the various films ranged from 15 min. to about one hour.

Applicants respectfully submit that Tapolsky et al is different from the claimed invention for at least the following reasons:

1. Tapolsky focuses on common drugs and not herbal medicines that have to be prepared for use in the formulation. No herbals or homeopathics were mentioned or suggested in Tapolsky.

2. The films of Tapolsky are prepared by casting a solution and drying in the oven. This process resulted in a poor adhesiveness which, at best, only lasts for minutes in most cases. On the other hand, the compositions of the present invention are prepared by a process of compression molding of powders which provide the preferred consistency for better adhesion that can last for a few hours.

3. In Tapolsky, the use of heat for drying (9 min at 130°C) may destroy the active agents. In the case of herbal medications, this heat drying will result in the evaporation and degradation of the many actives that compose the medication. The process of the present invention is carried out at room temperature or below which does not affect the herbal agent. Applicants' Claim 1 recites a therapeutically effective amount of at least one herbal active agent or homeopathic active agent.

Thus the process described in said patent to Tapolsky et al does not produce the compositions claimed in the present application and therefore can not be viewed as a teaching thereof. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

Claims 1, 4-7, 9, 15-17, 19, 22 and 23 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Roreger et al. (US 5,456,745) with evidence provided by Lawless for the reasons stated in the Office Action.

The Examiner asserts that Roreger teaches, e.g., a hydrophilic insoluble gel film for topical application that adheres to oral mucosal tissue comprising a therapeutically effective amount of at least one herbal, 0.05 to 30%-weight of at least one anionic water-soluble polymer, and 0.05 to 30%-weight of at least one cationic water-soluble polymer.

The Examiner recognizes that the second example (i.e., Example 24) taught by Roreger does not teach that the composition can be used in the manner instantly claimed, however, the Examiner asserts that the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference

composition. The Examiner states that in order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the Examiner states that the intended use does not create a structural difference, thus the intended use is not limiting.

Applicants respectfully traverse and submit that the reference does not anticipate the claimed subject matter.

Applicants submit that Roreger describes certain films that swell in aqueous medium prepared from water soluble anionic polymer, cationic polymer, a moisturizer and water by casting a clear solution into sheets. The basis of this invention is the ability to mix together cationic and anionic polymers without precipitation using co-solvents, volatile additives, heat, etc. The films are suggested for use as a dressing for damaged skin and ulcers of the leg (Column 6). The examples describe film formation with detailed formulations that include common cationic and anionic polymers, salts etc. However, the films have no adhesive properties; they were not used in the oral cavity; and they do not release active agents, although they may contain preservatives and stabilizers. Herbal extracts are mentioned in Example 21, where myrrh and sage tinctures were added to the film composition.

Applicants submit that Roreger is not related to the present application because it describes non bioadhesive films for use as dressings on skin ulcers and has no relation to an oral adhesive patch.

Based on the distinctions presented above and arguments against anticipation, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102.

Alternatively, if such withdrawal is not granted, Applicants submit that the multiple rejections presented in the last Office Action were improperly multiplicious and submit that only the best anticipation reference should be maintained and that the other references should be withdrawn for each claim.

Claim Rejections - 35 USC § 103

Claims 1-5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tapolsky et al. for the reasons stated in the Office Action.

The Examiner recognizes that Tapolsky does not expressly teach a solid, self-bioadhesive composition comprising the instantly claimed measurements. However, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the thickness and the diameter of the composition taught by Tapolsky because Tapolsky teaches the requisite ingredients and amounts of ingredients, the residence times for effective drug delivery, and process steps for making the layers of the referenced composition, which can be used in the making of a disc having varying measurements of thickness and diameter.

Applicants respectfully traverse by submitting that for at least the same reasons that Tapolsky does not anticipate the claimed invention, Tapolsky does not render Applicants' invention obvious therefrom.

Claims 1-11, 15-17, 19, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tapolsky et al. in view of Iyer et al. (US 5,939,050) and Friedman et al. (US 6,197,305) with evidence provided by Lawless for the reasons stated in the Office Action.

The Examiner recognizes that Tapolsky does not teach the claimed invention wherein the herb tincture active agents are selected from the Markush group recited in Claim 6, wherein the herb essential oils active agents are selected from the Markush group recited in Claim 7, wherein the essential oil comprises at least one monoterpene with three unsaturations, wherein said essential oil is a natural or synthetic mixture consisting of limonene, myrcene, a-pinene, b-pinene, sabinene characterized in that at least 60% by weight is limonene, and wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomelo and citron.

Applicants respectfully traverse the obviousness rejection combining Tapolsky with the cited secondary references.

Friedman et al '305 describes certain herbal compositions with antifungal activity. The patent describes certain mixtures of extracts and oils that have been tested for their antifungal activity against common fungi, Candida, aspergilus. These mixtures have been formulated into fat base ointments composed of beeswax, Stearyl octanoate, and safflower oil. Throughout the text there is no mention of an oral application or an adhesive.

This patent is not related to the present application because:

1. It does not mention a bioadhesive patch for treating the oral cavity.

2. The focus of this patent is certain herbal compositions having antifungal activity using ointment for application.

Furthermore, Iyer et al describes various compositions that contain herbal agents; the compositions are not in tablet form; they are not bioadhesive; and the amount of bioadhesive polymer in these formulations is less than 0.5% which has no bioadhesive effect. There is no local administration of the agents, and it is used for full oral cavity spread.

For the above reasons, each of the cited references is quite different from the invention and does not anticipate Applicants' claimed invention. Moreover, even if the cited references are combined, it is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to select the inventive solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue to improve a known problem in the art.

Claims 1-6, 12, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Tapolsky et al. and Friedman et al. (US 6,197,305) in view of Shuch et al. (US 6,207,137) for the reasons stated in the Office Action.

The Examiner recognizes that Tapolsky does not teach a solid, self-bioadhesive for topical application comprising herb tincture active agents selected from the recited Markush group of Claim 6, and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCL and mixtures thereof. However, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients to the composition taught by Tapolsky because Friedman teaches antifungal compositions comprising botanical tinctures which can be used in the making of therapeutic oral

compositions and Shuch teaches compositions comprising homeopathic salts and herbal botanicals which can be used in the making of therapeutic oral compositions.

Applicants respectfully traverse by submitting that for at least the same reasons that Tapolsky does not anticipate the claimed invention, the secondary references do not overcome the differences in Tapolsky discussed above. Tapolsky combined with secondary sources does not render Applicants' invention obvious therefrom.

Applicants further submit that Shuch et al describes dental formulations, but does not disclose, teach or suggest stickers or bioadhesive devices for treating local ulcers.

In view of the Applicants' arguments presented above against obviousness, Applicants' respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE

23373
PATENT TRADEMARK OFFICE

Date: April 17, 2003

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims are amended as follows:

1. (Amended) A solid, self-bioadhesive composition for topical application that adheres to [the] oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent or homeopathic active agent; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition.

2. (Amended) A solid composition according to claim 1 wherein said composition is in the form of a disc of 2-15 mm diameter and 0.4 to 2.3 mm thick that adheres to oral mucosal tissue for at least 30 minutes.

3. (Amended) A solid composition according to claim 1 wherein said composition is in the form of a disc of 5-11 mm diameter and 1 to 2 mm thick with tissue adherence of at [least1] least 1 hour.

4. (Amended) A composition according to claim 1, wherein the herbal active agent is at least one selected from the group consisting of an [either] anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, and an antiparasite agent [and combinations thereof].

5. (Amended) The composition of claim 1, wherein the [herb active agents are] herbal active agent is selected from the group consisting of a bioactive herb extract[s], a tincture[s], an essential oil[s] and [mixture] mixtures thereof.

6. (Amended) A composition according to claim [3] 1, wherein the [herb tincture active agents are] herbal active agent or homeopathic active agent is at least one selected from the group consisting of[:] Gotu Kola, Echinacea, Salvia [offinc.] officinalis, Hypericum, [Myrrah] Myrrh, Camphoria, Uncaria, Elder, Plantago, Baptisia, Calendula, [Phytolaca] Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis, Sage[.], [Barberine] berberine from hydrastis canadensis L., [and other berberidaccae] plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, and Radix gentianae Longdancao antifungal agent [and combinations thereof].

7. (Amended) The composition of claim 5, wherein the [herb essential oils active agents are] herbal active agent is at least one essential oil selected from the group consisting of[:] citronella oil, lemon oil, citron oil, [pomela] pomelo peel oil, [cedrwood] cedarwood oil, juniper berries oil, lemon basil oil, [rosmarinus offencinalis] Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrte oil, [origano] oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil.

8. (Amended) The composition of claim 5 wherein the herbal active agent is at least one essential oil [is] selected from the group consisting of cinnamon oil, tea-tree oil and citronella oil [and mixtures thereof].

9. (Amended) A composition according to claim [7]6, wherein [said essential oil] the herbal active agent comprises at least one monoterpene with three unsaturations.

10. (Amended) A composition according to claim [9]5, wherein [said] the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene[,] and at least one of myrcene, a- pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. (Amended) A composition according to claim 9, wherein said monoterpenes with three unsaturations is [of] at least one citrus oil selected from the group consisting of lemon, [pomella] pomelo and citron.

13. (Amended) A composition according to claim 6, further comprising Carnallite [in a synergistic and effective amount].

14. (Amended) A composition according to claim 13, wherein said Carnallite is present in an amount of about 5-50% wt/wt [of the active] based on the amount of the at least one herbal active agent or homeopathic active agent [composition].

15. (Amended) The composition of claim 1, further comprising a non-herbal active agent selected from the group consisting of anesthetic agent, analgesics, steroidal and non-[stroidal] steroidal anti-inflammatory agents, antihistaminic or antiallergics, steroids,

antimicrobial drugs, vitamins, enzymes, anti-allergic drugs, antipyretics, antimalarial, antiulcer drugs, peptides, DNA plasmid and antisense based therapeutic agents[,].

16. (Amended) The composition of claim 15, wherein the anesthetic agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacaine, and etidocaine [and is in the form of the base or an acid-addition salt or both forms].

17. (Amended) The composition of claim 15, wherein the non-herbal active agent [consists] is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, [and the like,] amphotericine B, nystatin, itraconazole, [and the like,] chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes[, is in the form of the base or an acid-addition salt or both forms].

18. (Amended) The composition of claim 4, further comprising [wherein salts comprising of] Carnallite [and its individual salts are used to] or a salt of Carnallite, which [improve] improves the activity of the herbal active agents.

19. (Amended) The composition of claim 4, wherein the herbal active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations [comprising of:] selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene[, and the like].

20. (Amended) The [active agent] composition of claim 15 comprising a [cirton] citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1.

21. (Amended) The [active agent] composition of claim 15 comprising a [cirton] citron oil and Carnallite salt at a weight ratio between 1:10 to 1:1 and a local anesthetic [such as] selected from the group consisting of lidocaine, benzocaine, [or] and bupivecaine.

22. (Amended) The composition of claim 1, wherein the [self-bioadhesive] solid bioadhesive carrier is selected from a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.

23. (Amended) The composition of claim 22 wherein said polyhydric polymer comprises at least one member selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, [gaur-gum] guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymers of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers, and mixtures thereof.

24. (Amended) A composition according to claim 22 in the form of a tablet wherein said [adhesive] composition additionally contains one or more members selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme [enyzme] inhibitors, and lubricants.

25. (Amended) A composition according to claim [22] 24 wherein said enhancers are selected from salts of bile acids[, limonene]and limonene [derivatives].

26. (Amended) A composition according to claim 22 wherein said solid bioadhesive carrier [are] is selected from polyacrylic acid polymers lightly crosslinked with a polyalkenyl

polyether, [and cellulose derivatives] carboxymethylcellulose, hydroxymethylcellulose and mixtures thereof.